NCATS Improving Health Through Smarter Science

CTSA Program Steering Committee

Monday, August 13, 2018

2:30 – 4:00 ET

CTSA Clinical & Translational Science Awards Program

National Center for Advancing Translational Sciences

Agenda

2:30	Welcome	Kathleen Brady and Michael Kurilla
2:30 – 2:40	NCATS Director's Update	Michael Kurilla *on behalf of Christopher Austin*
2:40 – 2:50	In-Person Program Meeting Update	Clare Schmitt
2:50 – 3:05	Preliminary DTF Survey Aggregate Report	Deborah Ossip (CLIC)
3:05 – 3:10	Discussion: Request to Add Administrator to Steering Committee	Introduction by Erica Rosemond Discussion by all
3:10 – 3:30	Discussion: Buprenorphine Waiver Training **Review:** (NEJM) Primary Care and the Opioid-Overdose Crisis — Buprenorphine Myths and Realities	Introduction by Michael Kurilla and Kathleen Brady Discussion by all
3:30 – 4:00	Pod Feedback Round Robin	All

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Welcome new SC Member: Harold Collard, M.D.

Dr. Jennifer Grandis

Dr. Harold Collard

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NCATS Director's Update – FY 2019 Budget

House - Appropriations Subcommittee on Labor/HHS/Educ

- June 14 - passed Bill (https://appropriations.house.gov/files/?CatagoryID=34777)
  - Bill Details:
    - NIH: $38.3 billion (+ $1.25 billion)
      - NCATS: $751,219,000 (+ $8.9 million)
        - CAN: up to $30,000,000
        - CTSA: $542,771,000 (+ $0)
  - Report Details:
    - "The Committee expects NIH to fund CTSAs at not less than the level provided in FY 2018."
    - "Rural Health Outcomes and Health Disparities--…The Committee requests an update on the actions within the CTSA Program to improve rural health outcomes and health disparities in the FY 2020 [budget request]."
- July 11 - Full Appropriations Committee approved Bill

Senate - Appropriations Subcommittee on Labor/HHS/Educ

- June 26 - passed Bill (https://www.appropriations.senate.gov/subcommittees/labor-health-and-human-services-education-and-related-agencies)
  - Bill Details:
    - NIH: $39.1 billion (+ $2.0 billion)
    - NCATS: $806,787,000 (+ $64,353,000)
      - CAN: up to $80,000,000
      - CTSA: $560,031,000 (+17.3 million)
  - Report Details:
    - "The Committee encourages the NCATS to fund, through the existing CTSA Program hubs, expanded efforts to improve translational research that address health disparities and the significant burden of conditions that disproportionately affect minority and special populations..."
- June 28 – Full Appropriations Committee approved all 12 FY19 appropriations bills.

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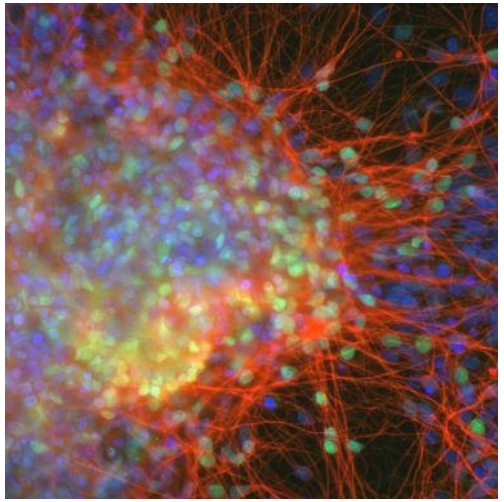
Funding Opportunities: Regenerative Medicine Innovation Project



- Title: RMIP Investigator-Initiated Research Project
  ID Number: RFA-HL-18-030
  Activity Code: U01 – Clinical Trial Not Allowed
  Earliest Submission Date: September 19, 2018
  Application Due Date: October 19, 2018
- Title: RMIP Investigator-Initiated Clinical Trials
  ID Number: RFA-HL-18-031
  Activity Code: UG3/UH3 – Clinical Trial Required
  Earliest Submission Date: September 19, 2018
  Application Due Date: October 19, 2018
- Title: RMIP Small Business Technology Transfer Cooperative Agreement
  ID Number: RFA-HL-18-033
  Activity Code: UT2 - Clinical Trial Not Allowed
  Earliest Submission Date: September 19, 2018
  Application Due Date: October 19, 2018
- Title: RMIP Small Business Innovation Research Cooperative Agreement
  ID Number: RFA-HL-18-035
  Activity Code: U44 - Clinical Trial Not Allowed
  Earliest Submission Date: September 19, 2018
  Application Due Date: October 19, 2018

For more information visit: https://www.nih.gov/research-training/medical-research-initiatives/rmi

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In-Person Program Meeting Update

Clare Schmitt

CTSA Program Meetings

- **Fall CTSA Program Meeting**
  - Focus: Priority research issues and opportunities for the consortium members to come together to share best practices
    - Day 1
      - Steering Committee
      - Administrators' Meeting
    - Day 2
      - Annual Program Meeting

- **Spring CTSA Program Meeting**
  - Focus: Education and training for the TS workforce and DTFs
  - Spring 2019
    - TL1 and KL2 meetings
    - DTF meetings
    - CTSA Program Steering Committee
  - Adjacent to ACTS Meeting, Martin and ACTS President Bob Kimberly are in discussions

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2018 Fall CTSA Program Meeting

- Report from participants of Spring Meeting
  - More networking time
  - Less reports out (use PI webinar / newsletter for this)
  - More discussion of best practices
- Planning Committee
  - The Steering Committee with NCATS
- Place
  - Hilton Crystal City at Washington Reagan National Airport Arlington VA
- October 22
  - SC Meeting
  - Administrators Meeting
- October 23
  - CTSA Program Meeting
- More Info
  - https://clic-ctsa.org/events/2018-ctsa-program-fall-meeting

Strawman Agenda

- **Morning Session**
  - Updates from NCATS
  - Report from SC DTF Task Force
  - The Great CTSA Team Science Contest – Winners Announced
  - Presentation from SMARTIRB / ACT
- **Afternoon Sess**ion
  - Open solicitation from consortium of topics for best practices
- **Networking Opportunities**
  - 30 minute breaks – morning and afternoon
  - Longer lunch – with boxed lunches
  - Other

Timeline

Meeting and Date	Tasks
Now – August 8	• Solicitation of topics for the afternoon session should be submitted through the CLIC Suggestion Box (use the drop-down "Suggestion for CTSA Program Meeting"): https://clic-ctsa.org/contact/suggestion-box • Topics from the PIs, SC, consortium
August 13 (SC Meeting)	• SC will review topics • SC will determine the need for presenters or discussion leads
September 10 (SC Meeting)	• If solicitation extended: SC will review topics and determine the need for presenters or discussion leads • Finalize agenda and disseminate
October 23	• Fall CTSA Program Meeting takes place

Suggestions Received for Afternoon Session

Suggestion	Submitter (Presenter)
Report out of best practices from FY17 sIRB administrative supplements: • September 12 NIH Workshop entitled "sIRB Review for Multi-Site Research Resource and Infrastructure Development"? The proposed presentation(s) at the October Program Meeting could include the outcomes of the Workshop, about which a paper is planned.	Valery Gordon (Kathleen Brady)
• Update from CD2H and how hubs should plan on engaging them. • Metrics around the TIN. How many studies have been proposed? (etc) • Successful strategies around team science • TIN efforts around assisting with setting up and managing central IRBs and Irex	Keith Herzog (Donald Lloyd-Jones) (Northwestern and Pod members)
• CHAMP (Child Health research Acceleration through Multisite Planning) • Common metrics (particularly the IRB duration data) • The concept of "NCATS Designation," as is done by the NCI for its cancer centers	Dan Cooper (Dan Cooper) (UCI and Pod members)

Suggestion	Submitter (Presenter)

• Clinical research units
  • Pricing for services to investigators
  • How are the units run
  • How do units integrate within sections as specified in the CTSA renewal FOA
• DIAMOND
• Project Oversight / management of cores – Successes and challenges:
  • Community engagement
  • Bioinformatics
  • K and T programs
  • Workforce
• Integrating clinical care and research
  • How to change the prevailing attitude about participation in health research to universal participation, so that enrollment in clinical care and health research are intertwined.
• Affiliation and governance models
  • Special interest in those models with multiple institutions that comprise a CTSA hub/consortium
  • Ways in which institutions within a hub have been successful in working together
• Common Metrics
  • Interpretation of summary reports as recently distributed
  • Discussion about ways to improve the reports going forward
	Mary Sienkiewicz (Tim Murphy) Pod: University at Buffalo, Stanford University, Johns Hopkins University, University of Washington, University of Arkansas, Weill Cornell Medicine and University of Chicago

Suggestions Received for Afternoon Session

Suggestion	Submitter (Presenter)
Opportunities to enhance the interactions between the Preclinical Innovation component of NCATS and the CTSA Program	Barry Coller (Mod Pod)
Opportunities for CTSA Hub Engagement with CD2H Opportunities for CTSA Hub Engagement with CD2H	Melissa Haendel (Melissa Haendel)
Suggested Speaker - Jason Owen-Smith, IRIS: Novel Approaches to Evaluating CTSA Educational Programs	George Mashour

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PRELIMINARY DTF SURVEY AGGREGATE REPORT

Steering Committee Update
13 August 2018

Deborah J Ossip PhD
Martin Zand MD PhD

The University of Rochester Center for Leading Innovation and Collaboration (CLIC) is the coordinating center for the Clinical and Translational Science Awards (CTSA) Program, funded by the National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH), Grant U24TR002260.

DTF Survey Overview

- **Created by:** NCATS CTSA Program Steering Committee Work Group on Domain Task Forces (DTFs) in collaboration with CLIC
- **Goals:**
  - To obtain feedback from PIs, Administrators, DTF members, and DTF Work Group Members on structure and function of DTFs
  - To inform changes to enhance and improve operations
- **Data Collection:**
  - 2 July - 16 July 2018

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Domains Assessed

1. Descriptors: Role; DTF and DTF Work Group Membership
2. Individual DTF Satisfaction
3. Overall DTF Structure
   - What works well
   - What can be improved
   - Suggested areas
4. Suggested Name Change

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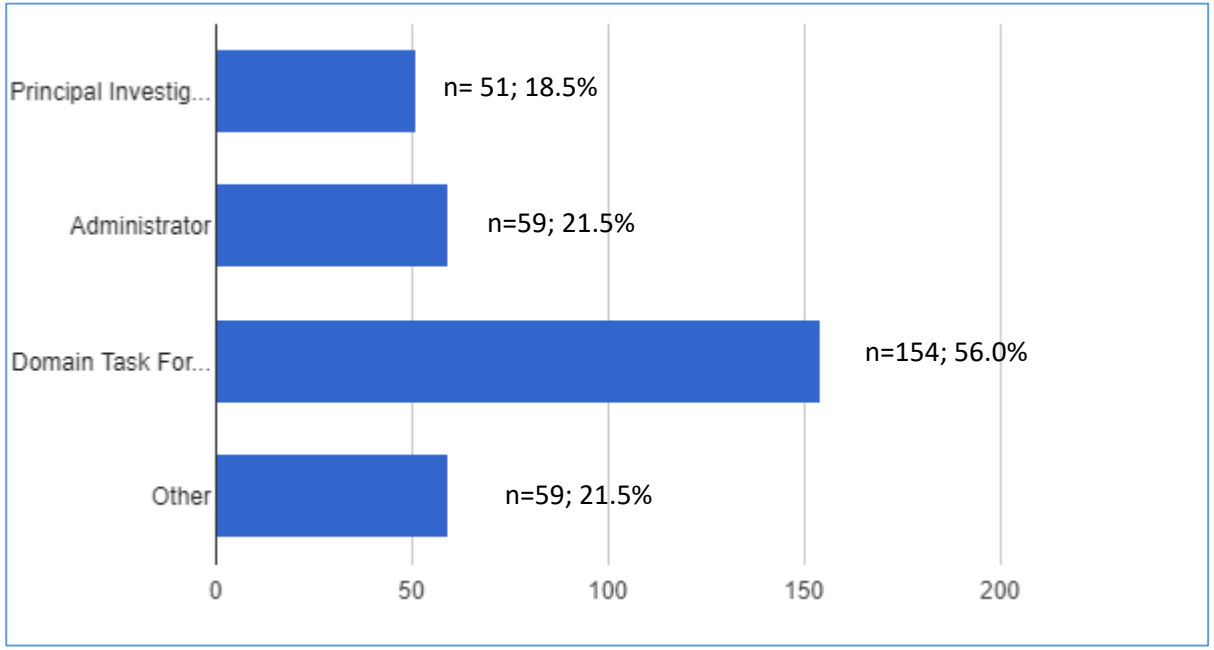
Respondents

- REDCap link sent to PI, Administrator, DTF and DTF Work Group listservs
- 1,250 valid emails
- 275 responses (22% response rate)



Examples of Other: TL1/KL2 PI, Research Scientist, Other Faculty, Evaluator, Executive Director

DTF	N	%
Workforce Development	55	27.4
Lifespan Integration	29	14.4
Methods & Processes	60	29.9
Collaboration & Engagement	53	26.4
Informatics	34	16.9

146 (53.7%) were a member of at least one DTF Work Group

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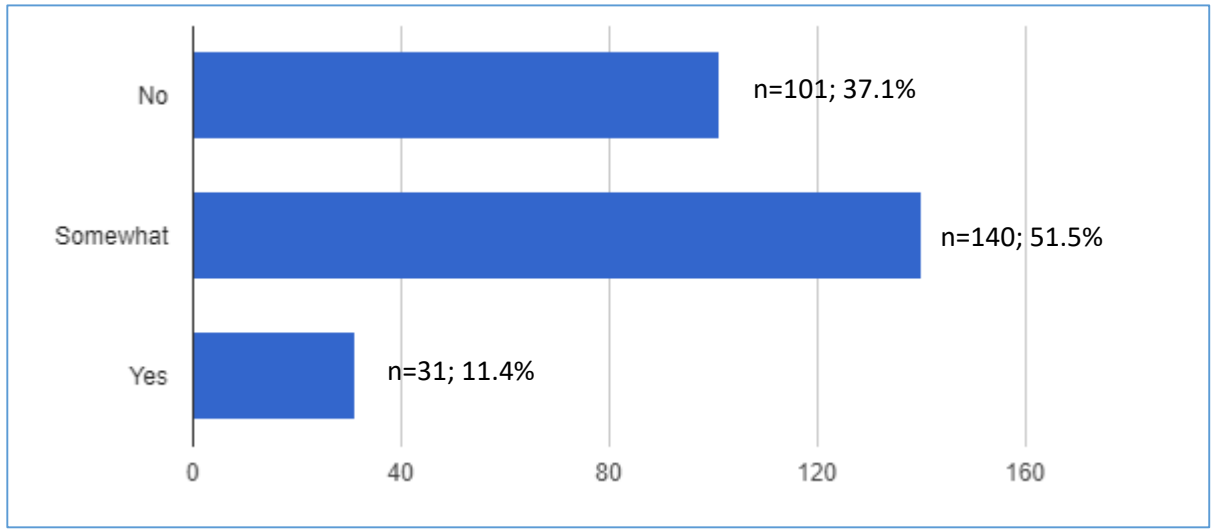
Do you feel you are well informed about the activities of the DTFs?



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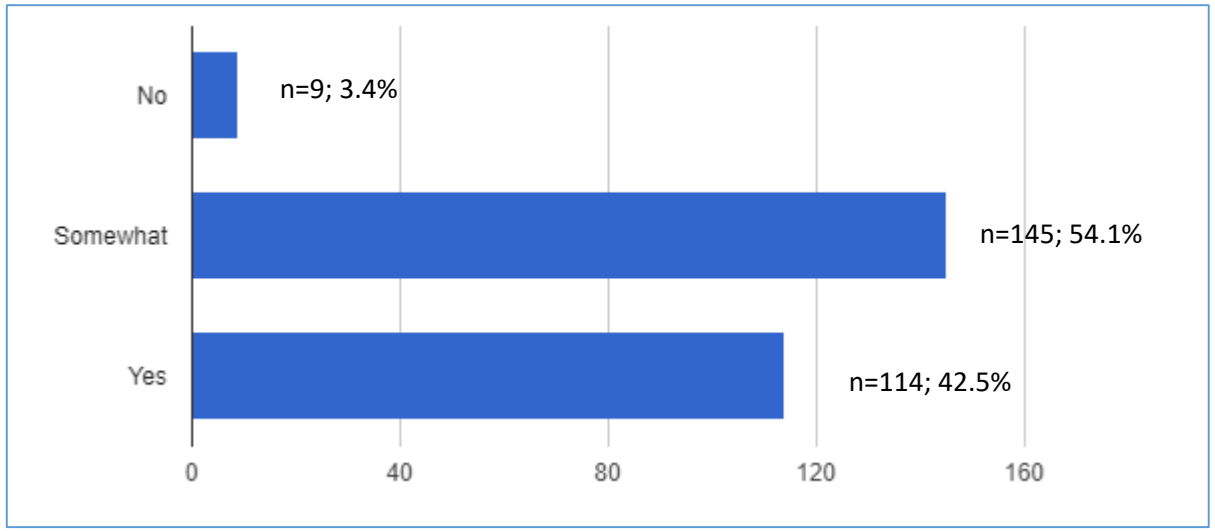
Are the DTFs Addressing Issues that are of Importance to Clinical and Translational Science and to the CTSA Program Consortium?



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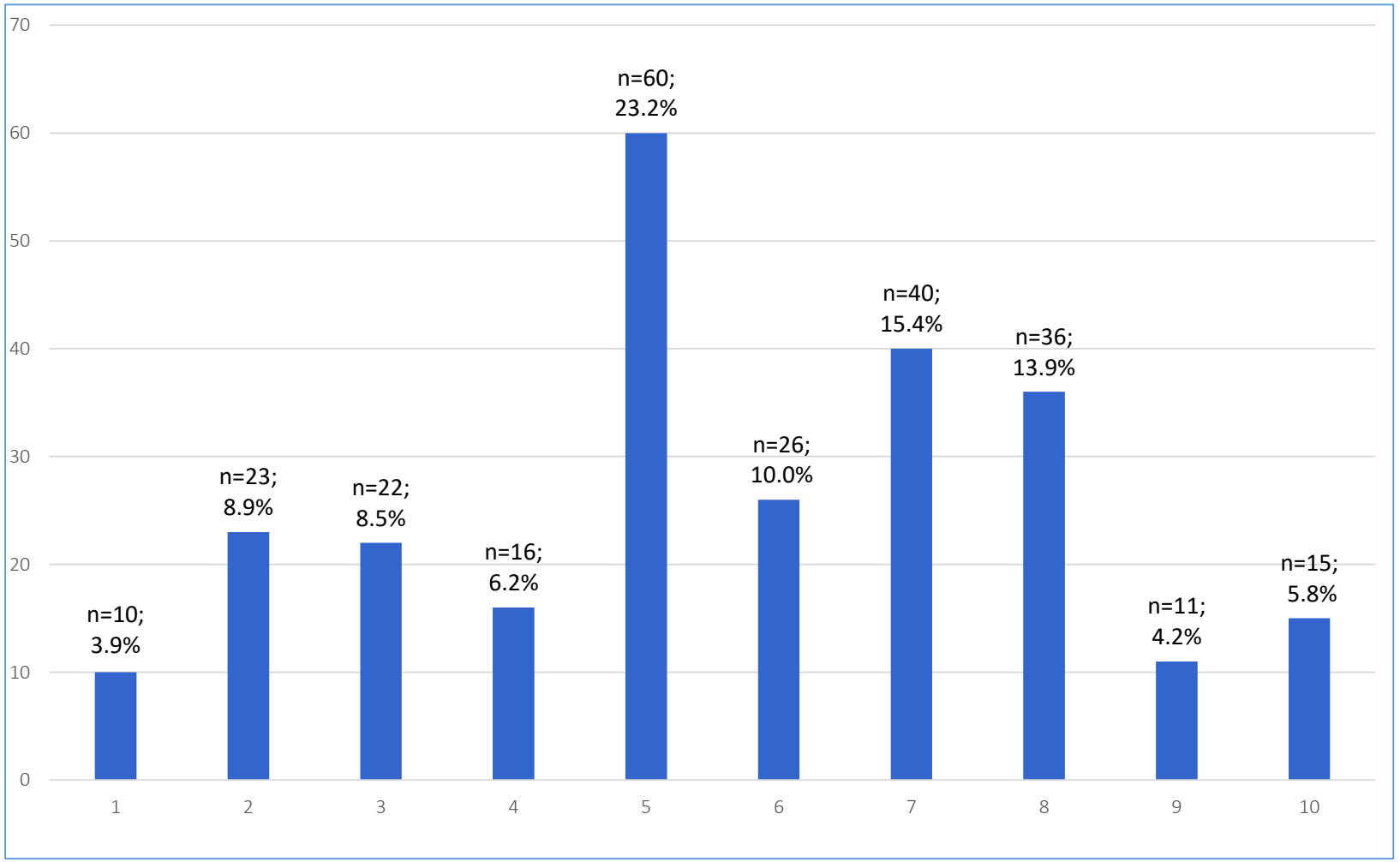
How Valuable are the DTFs?



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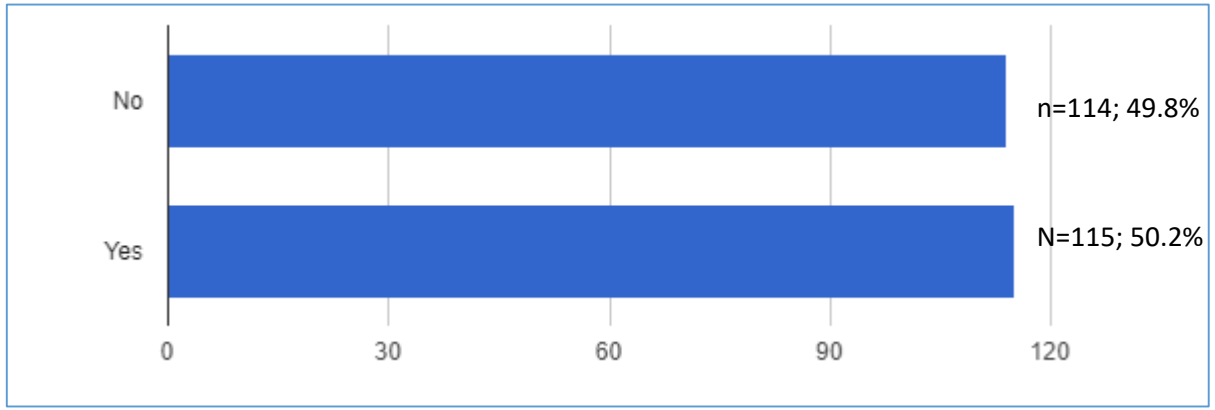
Is the Current DTF Structure (as Outlined in the DTF Governance Document) the "Right" Structure?



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What Works Well?

Themes (5)	#	Sample Quotes
Communication and Information Sharing	18	*The group communicates in a robust manner and doesn't hold back on sensitive subjects.* *The discussion of the DTF conference calls are very open and welcoming.* *[The DTF] gets the word out on initiatives that all hubs should be aware of.* *CLIC is working very well.*
Collaboration and Inclusion	18	*The DTF works well as a way to connect, catalyze and potentially collaborate through working groups of individuals with similar interests* *Each DTF seems free to set their own agenda while still following NCATS's guidance about relevant priorities.* *Greatly appreciate that DTF is inclusive for administrators attending as PIs may not be able to attend.*
DTF Leadership	11	*Leadership is clear and I think the structure makes sense.* *Strong but peer elected leaders, adequate support of DTFs through centralized staff, enthusiastic membership.* *The Lead Team structure provides a way for work related to the overall DTF to be accomplished, since the entire DTF is too large to effectively work together on "projects."*
Small Groups	5	*Assigning smaller groups to work on projects with a lead person(s)* *I think the smaller, fixed project/time activities work well where a 5-7 person group works on a deliverable*
Topics	4	*I think the right thematic topics are covered.* *It helps to identify the priority areas and gaps, coordinate and make plan to identify working groups.*

N=71

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What Can be Improved?

Themes (4)	#	Sample Quotes
Broad Goals	26	*It is hard to evaluate their work product in the present format.* *More emphasis on identifying a few specific high-priority issues for the Working Groups to focus on, then perhaps having smaller breakout groups with objective goals/outputs to work towards.* *Key thing to improve: clearly defined scope of work and potential outcomes from the DTFs.*
Communication	24	*I think there needs to be more feedback loops between and across the DTFs. While communication has enhanced SIGNIFICANTLY, I think there needs to be more between NCATS and the DTFs.* *[Need] a central summary, rather than maintaining multiple "threads."* *Too complicated, too many participants, too little clear communication. Can lose sight of broad DTF goals.*
Lack of Funding/Unfunded Mandate	17	*Either fund the projects, or support projects that are of interest to a broader audience.* *…the DTFs come across as an unfunded mandate and are not resourced to achieve truly meaningful collaborative projects.* *There has to be connection between DTF activities and priorities for future spending within the program.*
Conference Calls	12	*The phone calls don't really work well when you have 40+ people. Perhaps a fall regional meeting, occasionally aligning people for phone calls in regions to enhance interaction, video calls?* *On one call it was mentioned that the majority of CTSAs are not calling into the meetings.* *The update information could be disseminated through another channel; DTF calls could focus on more interactive or educational activities.*

N=97

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Are there Areas Not Currently Being Addressed that you Would Suggest for NCATS Consideration?

Themes (4+)	#	Sample Quotes
Right Domains, but…	27	*Addressing the right areas, but there is little material evidence of anything getting accomplished that has to do with the overarching goal of the CTSAs* *Yes they are addressing the right areas. Don't add more…it creates a lot more work and divides time/attention spent on other DTFs/working groups.* *Yes, however the dissemination from the DTF to the entire consortium is still lacking.*
Correct Areas not Covered	29	*Mentoring is ignored* *Missing the boat on team science.* *The DTFs are missing an important opportunity in Dissemination and Implementation Science.*
DTFs Should Further Facilitate Collaboration	13	*I wonder if the DTFs' goal should be "to advance CTSA Program objectives AMONG the 5 domains" vs. "WITHIN the five domains" (cross-cutting activity).* *Is there merit in teasing [Collaboration and Engagement] apart a little?* *We need to be able to pilot collaborations and push that untapped potential to the next level.*
Suggestions for new DTFs	12	*Evaluation (n=9)* *Administration (n=3)* *Team Science*
Other Specific Suggestions		

N=140

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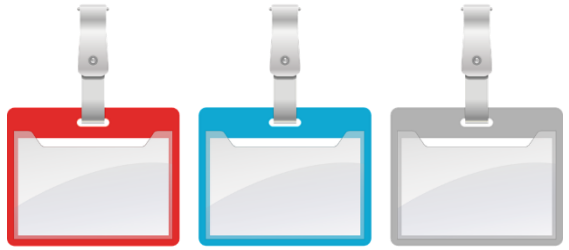
Suggested Name Change



Yes (49)		No (27)
Assemblies Collaborative Groups, Collaboratives Committees Core Enhancement Committees Cross-Domain Innovation Task Force CTSA Consortium Workgroups CTSA Innovation Network Groups CTSA National Committees Councils Domain Guidance Groups (DGGs) Domain Councils, Boards, Panels Domain Specific Collaborations Focus Areas, Focus Area Subgroups “Foundational” in name Innovation Forums Key Function Committees Key Strategic Initiatives	Objectives Task Force Priority Area Enhancement Committees Priority Infrastructure Committee Program Priority Committees Special Interest Groups, Interest Groups Steering Committee Strategic Goal Committee –SGC doesn’t appear to have objectionable meaning Task Force Translational Innovation Collaborative Translational Research Accelerator Coalition (TRAC) Translational Topics Action Groups (T-TAG) White Paper Teleconference Calls Working Group on …	*Name change seems less significant than increasing functionality and identifying funding sources/mechanisms* *I don’t think the name is as important as clarity in vision* *Please don’t change. It makes things confusing.* *I’m just getting used to DTF!* *My vote is to change the name if you are going to change the roles/organization*

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Next Steps

- Finalize report
- Circulate report to Steering Committee Work Group
- Post survey results on CLIC website

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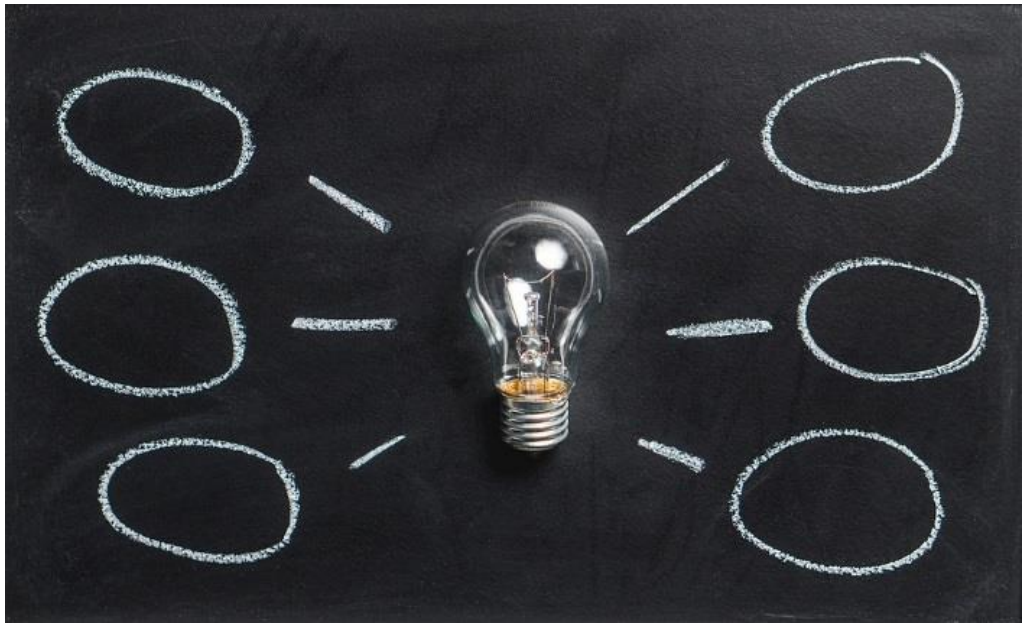

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Discussion Topics

Discussion Topics

3:05 – 3:10	Discussion: Request to Add Administrator to Steering Committee	Introduction by Erica Rosemond Discussion by all
3:10 – 3:30	Discussion: Buprenorphine Waiver Training **Review:** [(NEJM) Primary Care and the Opioid-Overdose Crisis — Buprenorphine Myths and Realities] Perspective Primary Care and the Opioid-Overdose Crisis — Buprenorphine Myths and Realities Sarah E. Wakeman, M.D., and Michael L. Barnett, M.D. Article Figures/Media Metrics 5 References 17 Comments Comments open through July 11, 2018 DESPITE WIDESPREAD awareness of the opioid-overdose crisis, the epidemic continues to worsen. In 2016, there were 42,249 opioid-overdose deaths in the United States, a 28% increase from the previous year. According to the National Center for Health Statistics, life expectancy in the United States dropped in 2016 for the second consecutive year, partly because of an increase in deaths from unintentional injuries, including overdoses. It was the first 2-year decline since the 1960s. How can we be making so little progress? Audio Interview Interview with Dr. Brendan Saloner on increasing access to medication for treatment of opioid use disorder. (06:51) Download July 5, 2018 N Engl J Med 2018; 379:1-4 DOI: 10.1056/NEJMp1802741 Related Articles PERSPECTIVE JUL 5, 2018 Moving Addiction Care to the Mainstream — Improving the Quality of Buprenorphine Treatment B. Saloner and Others PERSPECTIVE JUL 5, 2018 Methadone in Primary Care — One Small Step for Congress, One Giant Leap for Addiction Treatment J.H. Samet and Others	Introduction by Michael Kurilla and Kathleen Brady Discussion by all

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Pod Feedback

Summary of July Pod Feedback

- Enhanced interactions between the NCATS Division of Pre-Clinical Innovation and the Division of Clinical Innovation.
  - NCATS will take this into consideration when planning the upcoming fall CTSA Program meeting. DCI has been meeting with NCATS Intramural Division of Preclinical Innovation to better understand collaborative opportunities and entry points for potential projects initiated both within and outside of DPI as well as communication strategies for seamless transitions.
- Enhanced interactions between the CTSA Program and the IDeA Program
  - NCATS understands the need for enhanced collaboration with the IDeA Program. This specific topic is currently being addressed internally at NCATS as leadership is in active discussions with the new leadership of the recently reorganized NIGMS Division of Research Capacity Building, the home for the IDeA Program, to identify synergies and potential collaborations.
- Cancer-Center-like NCATS “designation”
  - Input from the CTSA Program in terms of features that uniquely define a CTSA Program brand will require some brainstorming and iteration of ideas.
- Domain Task Force Comments
  - “All of us are looking forward to the results of the survey and positive change in the DTF structure and function”
  - Suggestion: It seems that often if anything is produced, it is a white paper that gets put in a drawer. Could DTF WG white papers be bundled and published in a special issue of JCTS once a year (paid for by NCATS if needed)?

Summary of July Pod Feedback (Contd.)

- An NCATS “R01” Program
  - NCATS currently supports the CTSA Collaborative Innovation Awards (CCIA) program, which utilizes the U01 mechanism and the R21 mechanism. Other than the additional involvement of NIH staff that comes with a cooperative agreement (U), there is no meaningful distinction between this and an R01 program.

- Streamlining renewal applications
  - NCATS is developing a comprehensive multi-stakeholder plan to receive feedback about the existing funding opportunity announcement and the Program as a whole and will report back to the SC at a later time. In terms of the application format, NCATS can and has made requests to NIH to have changes be made to the form, content, and section requirements of grant applications, however these decisions are not under NCATS direct control. The funding opportunity mechanism has strict business rules that could not accommodate our requests. NCATS is also pursuing a long-term strategy of identifying the composition and attributes of a CTSA Program unique mechanism that will require agreement with NIH OER.

- Trial Innovation Network. What is NCATS doing to get other I/C's to use the TIN? Are there examples of specific PAs or RFAs that require the TIN to be engaged?
  - NCATS has given several recent presentations to trans-NIH groups and individual Institutes, Centers, and Offices about the TIN, and the TIN has received 126 proposals to date. Proposals investigating a variety of diseases and conditions continue to be submitted to trialinnovationnetwork.org from investigators seeking TIN support for studies pursuing or that have funding from thirteen different NIH Institutes and Centers, the Patient Centered Outcomes Research Institute (PCORI), or other funding sources. Several program officials at different ICOs have suggested investigators consider using the TIN as they develop their grant applications, and the TIN was just highlighted in NIH Open Mike blog.

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Summary of July Pod Feedback (Contd.)

- Concern about the quality of reviews and the sense that there was insufficient expertise on the review study section panels to appreciate what CTSAs do in the current environment.
  - NCATS considers the need to identify administrative and management efficiencies as part of its mandate to innovate, so NCATS welcomes carefully considered comments. NCATS would like to address any concerns and, is happy to consider legitimate changes that can be incorporated that do not increase the burden on applicants, reviewers, or staff.

Next call: September 10, 2018